Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: 8/24/2011

2. Sponsor
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3. Submission Correspondent
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4. Proposed Device Identification

   Proposed Device Name: Dental Laser Therapy System
   Proposed Device Model: penlase
   Classification: 2
   Product Code: GEX
   Regulation Number: 21 CFR 878.4810
   Review Panel: 878 General and Plastic Surgery

   Indication for use Statement:
   The ***PenLase*** is indicated for incision, excision, hemostasis, coagulation and vaporization of soft

tissue including the following indications:

- Excision and Incision Biopsies
- Hemostatic assistance
- Treatment of Apthous Ulcers
- Frenectomy
- Frenotomy
- Gingival Incision and Excision
- Gingivectomy
- Gingivoplasty
- Incising and Draining of Abscesses
- Operculectomy
- Oral Papillectomy
- Removal of Fibromas
- Soft Tissue Crown Lengthening
- Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Tissue retraction for Impression
- Vestibuloplasty

5. Predicate Device Identification

510(k) Number: k081214
Product Name: Styla microlaser / Styla Ortho
Manufacturer: Zap Lasers, LLC

510(k) Number: k093852
Product Name: iLase
Manufacturer: Biolase Technology, Inc.

6. Device Description

PenLase is a surgical equipment, simple tool, portable, reliable, and easy to use. It is a tool that can be used for the treatment of oral soft tissue surgery, plastic surgery.

The PenLase utilizes a semiconductor diode which consists of semiconductor "chips" made from Aluminum, Gallium and Arsenide, together commonly referred to as AlGaAs , with invisible infrared radiation as a laser source. The laser power is delivered to the treatment area via a fiber tip. The disposable fiber tips are bendable in a variety of angle for maximum access to all areas of the mouth.

PenLase delivers 0.7 Watts and 1.7 Watts with wavelength 810±10 nm of continue laser power without cords, outlets or foot switches, which makes its battery life last longer.

The PenLase charging station recharges up to two PenLase batteries simultaneously, a fully charged battery can last for several patients or procedures.

The ***PenLase*** is generally indicated for incision, excision, hemostasis, coagulation and vaporization of soft tissue including the following indications:

- Excision and Incision Biopsies
- Hemostatic assistance
- Treatment of Apthous Ulcers
- Frenectomy
- Frenotomy
- Gingival Incision and Excision
- Gingivectomy
- Gingivoplasty
- Incising and Draining of Abscesses
- Operculectomy
- Oral Papillectomy
- Removal of Fibromas
- Soft Tissue Crown Lengthening
- Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Tissue retraction for Impression
- Vestibuloplasty

Clinical Application:

Excision and Incision Biopsies	1.7W
Hemostatic assistance	0.7W
Treatment of Apthous Ulcers	0.7W
Frenectomy	1.7W
Frenotomy	1.7W
Gingival Incision and Excision	1.7W
Gingivectomy	1.7W
Gingivoplasty	1.7W
Incising and Draining of Abscesses	1.7W
Operculectomy	1.7W
Oral Papillectomy	1.7W
Removal of Fibromas	1.7W
Soft Tissue Crown Lengthening	1.7W
Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)	0.7W
Tissue retraction for Impression	1.7W
Vestibuloplasty	1.7W

Accessories list:

Accessories	Quantity
PenLase Main Handpiece	1
Charging Station, Power adapter	1
Laser Protective glasses	1
Patient goggle	1
Batteries	2pcs
Disposable Fiber tips(400um)	6pcs
OPERATION MANUAL	1
Laser warning sign	1
Quick Start Guide	1

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification, requirements.

IEC 60601-2-22: 1995, Medical Electrical Equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.

IEC 60601-1:1988+A1:1991+A2:1995, Medical Electrical Equipment – Part1: General requirements for safety.

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).

ISO 10993-5: 2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.

ISO 10993-10: 2002/Amd.1:2006, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.

8. Substantially Equivalent Conclusion

The proposed device, Dental Laser Therapy System, is determined to be Substantially Equivalent (SE) to the predicate device, Styla microlaser / Styla Ortho (k081214) and iLase (k093852), in respect of safety and effectiveness.

Analysis 1: The output power of proposed device is between that of the two predicates devices, and all of them comply with IEC 60825-1 and IEC 60601-2-22. So the difference will not affect the safety and effectiveness of the proposed device.

Analysis 2: the class of the aiming beam of proposed device is lower than that of the iLase, which means the proposed device has lower hazards. And all of them comply with IEC 60825-1 and IEC 60601-2-22. So the difference will not affect the safety and effectiveness of the proposed device.

Analysis 3: the Fiber tip diameter, beam diameter, spot size of proposed device are similar to that of the Styla Microlaser / Styla Ortho and iLase, and all of them comply with IEC 60825-1 and IEC 60601-2-22. So the difference will not affect the safety and effectiveness of the proposed device.

Analysis4: the button switch and foot switch are both intended to provide the handpiece on/off capabilities. And all of them comply with IEC 60825-1 and IEC 60601-2-22. So the difference will not affect the safety and effectiveness of the proposed device.

Analysis5: the dimension of the three devices does not affect the effectiveness of laser. And all of them comply with IEC 60825-1 and IEC 60601-2-22. So the difference will not affect the safety and effectiveness of the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 16 2011

China Daheng Group, Inc.
% Underwriters Laboratories, Inc.
Mr. Jeffrey D. Rongero
12 Laboratory Drive
Research Triangle, North Carolina 27709

Re: K113212
Trade/Device Name: Dental Laser Therapy System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 31, 2011
Received: November 01, 2011

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113212

Section II Indications for Use

510(k) Number:

Device Name: Dental Laser Therapy System

Indications for Use:

The ***PenLase*** is indicated for incision, excision, hemostasis, coagulation and vaporization of soft tissue including the following indications:

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- Operculectomy
- Oral Papillectomy
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- Soft Tissue Crown Lengthening
- Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Tissue retraction for Impression
- Vestibuloplasty

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Neil R Ogden for nxm

(Division Sign-Off)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113212